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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certified <i>[Signature]</i>

21 CFR Part 5

**Delegations of Authority and Organization; Center for Devices and Radiological Health**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the regulations for delegations of authority to reflect redelegations to other officials within the Center for Devices and Radiological Health (CDRH) pertaining to: Certifying true copies and using the Department seal, disclosing official records, issuing reports of minor violations, and medical device reporting procedures. This amendment is intended to reflect those redelegations.

**EFFECTIVE DATE:** *(Insert date of publication in the Federal Register.)*

**FOR FURTHER INFORMATION CONTACT:**

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**SUPPLEMENTARY INFORMATION:** FDA is amending the delegations of authority under § 5.22 *Certification of true copies and use of the Department seal* (21 CFR 5.22); § 5.23 *Disclosure of official records* (21 CFR 5.23); § 5.37 *Issuance of reports of minor violations* (21 CFR 5.37); and § 5.98 *Authority relating to medical device reporting procedures* (21 CFR 5.98) to reflect

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redelegations to other officials within CDRH. These redelegations will improve the efficiency of operations for the center.

Further redelegation of the authorities delegated is not authorized at this time. Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis.

### **List of Subjects in 21 CFR Part 5**

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

### **PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION**

1. The authority citation for 21 CFR part 5 continues to read as follows:

**Authority:** 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; 15 U.S.C. 1451–1461; 21 U.S.C. 41–50, 61–63, 141–149, 321–394, 467f, 679(b), 801–886, 1031–1309; 35 U.S.C. 156; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1, 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11921, 41 FR 24294, 3 CFR, 1977 Comp., p. 124–131; E.O. 12591, 52 FR 13414, 3 CFR, 1988 Comp., p. 220–223.

2. Section 5.22 is amended by revising paragraph (a)(10)(v) and by adding paragraph (a)(10)(vi) to read as follows:

#### **§ 5.22 Certification of true copies and use of Department seal.**

(a) \* \* \*

(10) \* \* \*

(v) The Director and Deputy Director, Office of Surveillance and Biometrics (OSB), CDRH, and the Director and Deputy Director, Division of Surveillance Systems (DSS), OSB, CDRH.

(vi) Freedom of Information Officers, CDRH.

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3. Section 5.23 is amended by adding paragraph (c)(5) to read as follows:

**§ 5.23 Disclosure of official records.**

\* \* \* \* \*

(c) \* \* \*

(5) The Director and Deputy Director, Office of Surveillance and Biometrics (OSB), CDRH, the Director and Deputy Director, Division of Surveillance Systems (DSS), OSB, CDRH, and the Chief Reporting Systems Monitoring Branch, DSS, OSB, CDRH.

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3. Section 5.37 is amended by adding paragraphs (a)(2)(iv) and (b)(4) to read as follows:

**§ 5.37 Issuance of reports of minor violations.**

(a) \* \* \*

(2) \* \* \*

(iv) The Director and Deputy Director, Office of Surveillance and Biometrics (OSB), CDRH, and the Director and Deputy Director, Division of Surveillance Systems (DSS), OSB, CDRH.

\* \* \* \* \*

(b) \* \* \*

(4) The Director and Deputy Director, OSB, CDRH, and the Director and Deputy Director, DSS, OSB, CDRH.

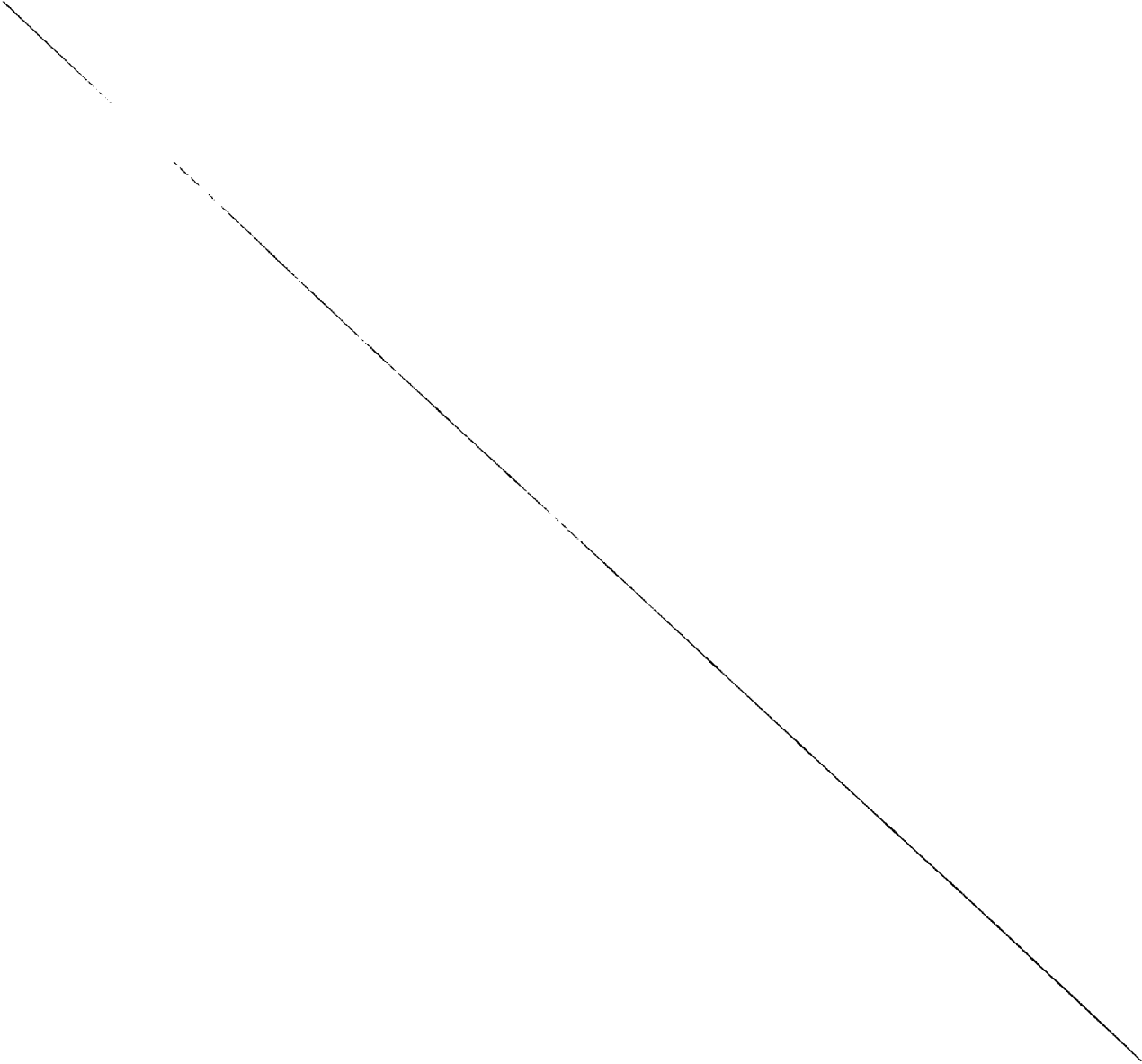
\* \* \* \* \*

5. Section 5.98 is revised to read as follows:

**§ 5.98 Authority relating to medical device reporting procedures.**

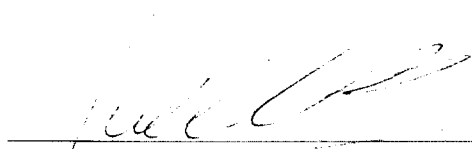
(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), the Director and Deputy Director, Office of Surveillance and Biometrics, (OSB), CDRH and the Director and Deputy Director, Division of Surveillance Systems (DSS), OSB, CDRH, are authorized to approve electronic reporting under § 803.14 of this chapter.

(b) The Director and Deputy Directors, CDRH, the Director and Deputy Director, OSB, CDRH, and the Director and Deputy Director, DSS, OSB, CDRH, are authorized to request the submission of additional information under § 803.15 of this chapter.



(c) The Director and Deputy Directors, CDRH, the Director and Deputy Director, OSB, CDRH, and the Director and Deputy Director, DSS, OSB, CDRH, are authorized to grant or revoke exemptions and variances from reporting requirements under § 803.19 of this chapter.

Dated: January 22, 1999  
January 22, 1999

  
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William K. Hubbard  
Associate Commissioner for Policy Coordination

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